

907 KAR 3:250. Programs of All-Inclusive Care for the Elderly (PACE).

RELATES TO: KRS 205.520, 205.5605, 205.5606, 205.5607, 42 C.F.R. Part 460, 42 C.F.R. 489.100-489.104, 42 U.S.C. 1396a, 1396b, 1396d, 1396n

STATUTORY AUTHORITY: KRS 194A.030(2), 194A.050(1), 205.520(3), 205.5606(1), 205.6317

NECESSITY, FUNCTION, AND CONFORMITY: The Cabinet for Health and Family Services, Department for Medicaid Services, has responsibility to administer the Medicaid Program. KRS 205.520(3) authorizes the cabinet, by administrative regulation, to comply with any requirement that may be imposed, or opportunity presented, by federal law to qualify for federal Medicaid funds. 42 C.F.R. Part 460 establishes the federal requirements for PACE to provide comprehensive, capitated health services that enhance the lives of frail, older adults, and enable those adults to live in the community as long as medically and socially feasible. This administrative regulation establishes the department's coverage and reimbursement for Programs of All-Inclusive Care for the Elderly (PACE).

Section 1. Definitions. (1) "Emergency medical condition" is defined by 42 C.F.R. 460.100(c).

(2) "PACE" means Programs of All-Inclusive Care for the Elderly.

(3) "PACE program agreement" means an agreement that:

(a) Is between a PACE organization, the Centers for Medicare and Medicaid Services (CMS), and the department for the operation of a PACE program; and

(b) Meets the requirements of Section 7 of this administrative regulation.

(4) "Participant" means an individual who is enrolled in a PACE program.

(5) "Post stabilization care" is defined by 42 C.F.R. 460.100(e)(3)(i).

(6) "Restraint" means a physical or chemical restraint as defined by 42 C.F.R. 460.114(a)(1) and (2).

Section 2. PACE Participant Eligibility, Enrollment, Disenrollment, and Reinstatement. (1) To be eligible to enroll in a PACE program, an individual shall:

(a) Be fifty-five (55) years of age or older;

(b) Be determined by the department to meet a nursing facility level of care determination, pursuant to 907 KAR 1:022;

(c) Reside in the service area of a PACE organization;

(d) Be able to live in a community setting without jeopardizing the participant's health or safety; and

(e) 1. Be eligible for Medicaid services pursuant to 907 KAR Chapter 20;

2. Pay the full capitation payment if not eligible for Medicaid or Medicare; or

3. Pay the Medicaid portion of the capitation payment if eligible for Medicare but not Medicaid.

(2) The PACE program enrollment process shall be in accordance with 42 C.F.R. 460.152.

(3) In order to enroll in a PACE program, a participant shall sign an enrollment agreement, which shall include all information required by 42 C.F.R. 460.154.

(4) Upon enrollment, a participant shall receive the following information from the PACE organization:

(a) A copy of the enrollment agreement, which shall:

1. Be explained to the participant or their representative or caregiver in a manner that they understand; and

2. If there are any changes, be updated and provided to the participant, with an explanation

as required by subparagraph 1. of this paragraph.

(b) A PACE membership card as required by 42 C.F.R. 460.156; and

(c) Emergency information, which shall also be posted in the participant's home, identifying the individual as a PACE participant and explaining how to access emergency services.

(5) Enrollment in a PACE program shall be effective on the first day of the calendar month following the date the PACE organization receives the signed enrollment agreement.

(6) Enrollment shall be continued in accordance with 42 C.F.R. 460.160.

(7) A participant shall have the right to voluntarily disenroll from the program at any time without cause. Any disenrollment shall:

(a) Be processed on the monthly enrollment cycle; and

(b) Comply with 42 C.F.R. 460.162.

(8) Involuntary disenrollment shall:

(a) Be reviewed by the department to determine that the PACE organization has acceptable grounds for disenrollment, pursuant to 42 C.F.R. 460.164; and

(b) Be in accordance with 42 C.F.R. 460.166.

(9) If a participant is disenrolled from a PACE program, the PACE organization shall:

(a) Make appropriate referrals and ensure medical records are made available to new providers within thirty (30) days; and

(b) Work with CMS and the department to reinstate the participant in other Medicaid programs for which the participant is eligible.

(10) A previously disenrolled participant shall not be precluded from being reinstated in a PACE program.

Section 3. PACE Covered Services. (1) Pursuant to 42 C.F.R. 460.90, if an eligible Medicaid participant elects to enroll in a PACE program:

(a) Medicare and Medicaid benefit limitations and conditions relating to amount, duration, scope of services, deductibles, copayments, coinsurance, or other cost-sharing shall not apply; and

(b) The participant, while enrolled in the PACE program, shall receive Medicare or Medicaid benefits solely through the PACE organization.

(2) Pursuant to 42 C.F.R. 460.92, the following shall be included in the PACE benefits package and provided to participants as applicable:

(a) All Medicare-covered goods and services for which the participant would otherwise qualify;

(b) All Medicaid-covered goods and services for which the participant would otherwise qualify; and

(c) Other services that are necessary, as determined by the interdisciplinary team, to improve and maintain the participant's overall health status.

(3) Emergency medical services shall be covered as applicable and pursuant to Section 4 of this administrative regulation.

Section 4. Emergency Services. (1) A PACE organization shall:

(a) Establish and maintain a written plan to handle emergency care that provides for services including:

1. An on-call provider, available twenty-four (24) hours per day to address participant questions about emergency services and respond to requests for authorization of urgently needed out-of-network services and post stabilization care services following emergency services; and

2. Coverage of urgently needed out-of-network and post stabilization care services if:

a. The services are preapproved by the PACE organization; or

b. The services are not preapproved by the PACE organization because the PACE organization did not respond to a request for approval within one (1) hour of being contacted or cannot be contacted for approval;

(b) Ensure that the following are held harmless if the PACE organization does not pay for emergency services:

1. PACE participants;
2. CMS; and
3. The department; and

(c) Ensure that the participant, caregiver, or both, understand when and how to get access to emergency services and that prior authorization is not needed.

(2) Emergency services shall:

(a) Be provided if:

1. Services are needed immediately because of an injury or sudden illness; and
2. The time to reach the PACE organization or one (1) of its contract providers would cause risk of permanent damage to the participant's health; and

(b) Include inpatient and outpatient services that:

1. Are furnished by a qualified emergency services provider, other than the PACE organization or one (1) of its contract providers, either in or out of the PACE organization's service area; or
2. Are needed to evaluate or stabilize an emergency medical condition.

Section 5. Exclusions to PACE Covered Services. The following services shall not be covered under a PACE program:

(1) Any service that is not authorized by the interdisciplinary team, unless the service is deemed to be an emergency service;

(2) In an inpatient facility:

(a) Private room and private duty nursing services, unless medically necessary; and

(b) Nonmedical items for personal convenience, unless specifically authorized by the interdisciplinary team as part of the participant's plan of care;

(3) Surgery that is purely cosmetic in nature and purpose, and does not meet an exception pursuant to 42 C.F.R. 460.96(c);

(4) Experimental medical, surgical, or other health procedures; or

(5) Services furnished outside of the United States, except:

(a) In accordance with 42 C.F.R. 424.122 and 424.124; and

(b) As otherwise permitted pursuant to Title 907 KAR.

Section 6. PACE Organization Requirements. A PACE organization shall:

(1) Have an agreement as required by 42 C.F.R. 460.30 with CMS and the department in order to provide services pursuant to this administrative regulation;

(2) Meet all requirements established in 42 C.F.R. 460 Subpart E, 460.60 to 460.86;

(3) Comply with all requirements established in 907 KAR 1:671 and 907 KAR 1:672;

(4) Not provide services designated as excluded from the program pursuant to Section 5 of this administrative regulation;

(5) Establish and implement a written plan to furnish care that meets the needs of each participant in all care settings for twenty-four (24) hours a day, every day of the year and provide services pursuant to 42 C.F.R. 460.98;

(6) Provide at each PACE center, at a minimum:

(a) Primary care;

(b) Social services;

- (c) Restorative therapies, including physical and occupational therapy;
- (d) Personal care and supportive services;
- (e) Nutritional counseling;
- (f) Recreational therapy; and
- (g) Meals;
- (7) Operate at least one (1) PACE center in or contiguous to its defined service area with sufficient capacity to allow routine attendance by participants;
- (8) Ensure accessible and adequate services to meet participant needs;
- (9) Establish a written participant bill of rights, which shall:
 - (a) Be displayed:
 - 1. In English and any other principal languages of the community as required by 42 C.F.R. 460.116(c)(1); and
 - 2. In a prominent place within the PACE center; and
 - (b) Include all rights specified in 42 C.F.R. 460.112;
- (10) Ensure that the rights specified in subsection (9) of this section, as well as the participant's responsibilities and appeal rights, are conveyed to the participant in writing and explained in a manner understood by the participant or their representative upon enrollment pursuant to 42 C.F.R. 460.116 and 42 C.F.R. 460.124;
- (11) Protect and provide for the exercise of the participant's rights;
- (12) Pursuant to 42 C.F.R. 460.118, establish documented procedures to respond to and rectify a violation of a participant's rights;
- (13) Pursuant to 42 C.F.R. 460.114, limit the use of restraints to the least restrictive and most effective method available, regardless of whether the restraint is physical or chemical in nature;
- (14) Ensure that any restrained participant be continually assessed, monitored, and reevaluated;
- (15) Meet the following conditions if the interdisciplinary team determines that a restraint is needed to ensure the participant's physical safety or the safety of others:
 - (a) The restraint shall be imposed for a defined, limited time, and based upon the assessed needs of the participant;
 - (b) The restraint shall be imposed in accordance with safe and appropriate restraining techniques;
 - (c) The restraint shall be imposed only if other less restrictive measures have been found to be ineffective to protect the participant or others from harm; and
 - (d) The restraint shall be removed or ended at the earliest possible time;
- (16) Establish, implement, maintain, and evaluate an effective, data-driven quality improvement program, in writing, pursuant to 42 C.F.R. 460.130 and 460.132 and containing, all requirements contained in 42 C.F.R. 460.134;
- (17) Ensure that the quality improvement plan complies with 42 C.F.R. 460.130 and reflects the full range of services offered by the PACE organization, and take actions that result in improvements in the organization's performance in all types of care, including all requirements established in 42 C.F.R. 460.136;
- (18) Pursuant to 42 C.F.R. 460.138, establish one (1) or more committees with community input to:
 - (a) Evaluate data collected pertaining to quality outcome measures;
 - (b) Address the implementation of, and results from, the quality improvement plan; and
 - (c) Provide input related to ethical decision making, including:
 - 1. End-of-life issues; and
 - 2. Implementation of the Patient Self Determination Act pursuant to 42 C.F.R. 489.102;

(19) Comply with all requirements for the PACE organization in the enrollment process, disenrollment process, and reinstatement process pursuant to Section 2 of this administrative regulation;

(20) Establish and maintain a procedure to document the reasons for all voluntary and involuntary disenrollments, and that documentation shall be available for review by CMS and the department;

(21) Utilize the information received under subsection (20) of this section relating to voluntary disenrollments in the quality improvement program;

(22) Pursuant to 42 C.F.R. 460.196, post a notice of the availability of the results of the most recent review conducted pursuant to Section 9 of this administrative regulation and any plan of correction or response to that review, and make these results available for examination in a place readily accessible to participants, their families, caregivers, or representatives; and

(23) Maintain records, collect all data, report all required data and information, and comply with all other requirements contained in 42 C.F.R. 460 Subpart L, 460.200 to 260.210.

Section 7. PACE Program Agreement Requirements. (1) A PACE program agreement shall meet the requirements for authorization pursuant to 42 C.F.R. 460.30.

(2) The PACE program agreement between the department and a PACE organization shall include:

(a) All content required by 42 C.F.R. 460.32;

(b) The criteria used to determine if an individual's health or safety would be jeopardized by living in a community setting, pursuant to 42 C.F.R. 460.150(c)(2);

(c) The criteria for determining the continuing eligibility of a participant, pursuant to 42 C.F.R. 460.160(b)(3)(ii).

(d) Pursuant to 42 C.F.R. 460.202 and 42 C.F.R. 460.32(a)(11), a comprehensive list of data and information pertaining to the PACE organization's provision of participant care:

1. Collected by the PACE organization; and

2. To be furnished to CMS and the department in the manner, and at the time intervals, specified by CMS and the department.

(e) The specific eligibility conditions pursuant to Section 2 of this administrative regulation;

(f) Any additional terms and conditions agreed to by the parties, subject to limitations pursuant to 42 C.F.R. 460.32(b)(2); and

(g) Pursuant to 42 C.F.R. 460.32(a)(12), procedures for any adjustments to account for the difference between the estimated number of participants on which the prospective monthly payment was based and the actual number of participants in that month.

(3) A PACE program agreement shall be effective for one (1) contract year, but may be extended for additional contract years in the absence of a notice by a party to terminate, pursuant to 42 C.F.R. 460.34.

(4) The department shall limit the number of PACE program agreements pursuant to 42 C.F.R. 460.24.

Section 8. Interdisciplinary Team. (1)(a) Each PACE organization shall establish an interdisciplinary team that fulfills each of the positions described in paragraph (b) of this subsection at each PACE center to comprehensively assess and meet the individual needs of each participant.

(b) An interdisciplinary team shall meet the composition requirements of 42 C.F.R. 460.102(b) and be composed of at least a:

1. Primary care provider, who shall:

a. Furnish primary medical care to a participant; and

b. Be responsible for managing a participant's medical needs and overseeing a participant's use of medical specialists and inpatient care;

2. Registered nurse;
3. Master's-level social worker;
4. Physical therapist;
5. Occupational therapist;
6. Recreational therapist or activity coordinator;
7. Dietitian;
8. PACE center manager;
9. Home care coordinator;
10. Personal care attendant or their representative; and
11. Driver or their representative.

(2) A PACE organization shall assign each participant to an interdisciplinary team functioning at the PACE center that the participant attends.

(3) A PACE organization shall establish, implement, and maintain documented internal procedures pursuant to 42 C.F.R. 460.102(f) and consistent with the confidentiality requirements of 42 C.F.R. 460.200(e).

(4) An interdisciplinary team that complies with the requirements of 42 C.F.R. 460.102 shall be responsible for the initial assessment, periodic reassessments, plan of care pursuant to 42 C.F.R. 460.106, and coordination of twenty-four (24) hour care delivery, and shall meet all requirements of 42 C.F.R. 460.104.

(5) Each member of the interdisciplinary team shall:

- (a) Regularly inform the interdisciplinary team of the medical, functional, and psychosocial condition of each participant;
- (b) Remain alert to pertinent input from other team members, participants, and caregivers; and
- (c) Document changes of a participant's conditions in the participant's medical record consistent with documentation policies established by the medical director.

Section 9. PACE Organization Monitoring. (1) The department, in cooperation with CMS, shall conduct continued reviews of PACE organizations as appropriate, and shall take into account the quality of care furnished and the organization's compliance with all requirements of 42 C.F.R. 460, and Title 907 KAR.

(2) Continued reviews shall include on-site visits at least every two (2) years.

(3) The department, in cooperation with CMS, shall monitor the effectiveness of actions taken to correct deficiencies identified during a review pursuant to Section 10 of this administrative regulation.

(4) The results of a review conducted under this section shall be:

- (a) Promptly reported to the PACE organization, along with recommendations for changes to the organization's program; and
- (b) Made available to the public upon request.

Section 10. Corrective Actions Regarding the PACE organization. (1) The department shall have the authority, upon a determination by CMS or the department that the PACE organization is not in substantial compliance with 42 C.F.R. Part 460, to:

- (a) Condition the continuation of the PACE program agreement upon timely execution of a corrective action plan;
- (b) Withhold some or all payments under the PACE program agreement until the organization corrects the deficiency; or

- (c) Terminate the PACE program agreement.
- (2) Termination of the PACE program agreement by the department, including termination for cause, shall comply with 42 C.F.R. 460.50, as appropriate.
- (3) If a PACE program agreement is being terminated, the PACE organization shall:
 - (a) Follow all procedures regarding termination pursuant to the PACE program agreement; and
 - (b) Provide transitional care to participants and comply with all other requirements established pursuant to 42 C.F.R. 460.52.

Section 11. PACE Organization Payments. (1) The department shall make a monthly payment to a PACE organization. The payment shall be:

- (a) A prospective payment, based upon the estimated number of participants a PACE organization will provide services to in the relevant month; and
- (b) Subject to adjustment based on the estimated and actual number of participants who received services from the organization in a given month, as provided in the PACE program agreement.
- (2) The amount of the department's monthly payment to the PACE organization shall:
 - (a) Be less than the amount that the department would have otherwise paid for a participant under other state plan services providing the same level of care;
 - (b) Take into account the comparative frailty of PACE participants;
 - (c) Be a fixed amount, regardless of changes in a participant's health status; and
 - (d) Be open to renegotiation on an annual basis.
- (3) A PACE organization shall:
 - (a) Accept the negotiated payment as payment in full for Medicaid participants; and
 - (b) Not bill, charge, collect, or receive any other form of payment from the department or from, or on behalf of, the participant, except a:
 - 1. Payment with respect to any applicable liability under 42 C.F.R. 435.121 and 42 C.F.R. 435.831 and any amounts due under the post-eligibility treatment of income process under 42 C.F.R. 460.184; or
 - 2. Medicare payment received from CMS or from other payers, in accordance with 42 C.F.R. 460.180(d).
- (4) A PACE organization shall not charge a premium to a participant who is eligible for Medicaid.

Section 12. Appeals and Grievances. (1) An appeal of a department decision regarding a participant or applicant relating to the delivery of PACE services shall be in accordance with 907 KAR 1:563.

- (2) An appeal of a department decision regarding the eligibility of an individual for Medicaid services shall be in accordance with 907 KAR 1:560.
- (3) The following shall not be considered a sanction against a PACE organization and shall not be appealable:
 - (a) A voluntary moratorium;
 - (b) A decision not to renew a certification;
 - (c) A citation; or
 - (d) Denial of an initial certification.
- (4) A PACE organization's appeals shall be in accordance with 42 C.F.R. 460.122.
- (5) A PACE participant may register any grievance or complaint regarding a PACE service provision or a PACE organization by contacting the department via:
 - (a) Email at dmsweb@ky.gov; or

(b) Mail at Department for Medicaid Services, Division of Policy and Operations, 275 E. Main Street 6W-D, Frankfort, Ky. 40621.

Section 13. Federal Approval and Federal Financial Participation. The department's coverage and reimbursement of services pursuant to this administrative regulation shall be contingent upon:

- (1) Receipt of federal financial participation for the coverage and reimbursement; and
- (2) Centers for Medicare and Medicaid Services' approval of the coverage and reimbursement.

Section 14. Use of Electronic Signatures. The creation, transmission, storage, or other use of electronic signatures and documents shall comply with the requirements established in KRS 369.101 to 369.120. (47 Ky.R. 1159; eff. 2-11-2021.)